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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR		ATTORNEY DOCKET NO.
09/458,579	12/09/99	BRENNAN	M	3718-6

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EXAMINER	
SEHARASEYON, J	

ART UNIT	PAPER NUMBER
1647	12

DATE MAILED: 07/05/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary	Application No.	Applicant(s)	
	09/458,579	BRENNAN ET AL.	
	Examiner	Art Unit	
	Jegatheesan Seharaseyon	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 April 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *10-14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 15-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15)☐ Notice of References Cited (PTO-892)
16)☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4,5 & 11* .
18)☐ Interview Summary (PTO-413) Paper No(s). _____ .
19)☐ Notice of Informal Patent Application (PTO-152)
20)☐ Other:

DETAILED ACTION

2. Claims 1-21 are pending. Applicant's election with traverse of Group I, claims 1-9 and 15-21 in Paper No: 10 is acknowledged. Claims in Group I are directed to identification of compounds that regulate bodyweight and the molecular pathways involved in the regulation *in vitro*. However, in Group II test animals are used to identify compounds *in vivo* that regulate body weight. In Group III genetically modified animals are used to identify the compounds that regulate the body weight. Since Groups II and III involve *in vivo* methods they will be joined to form a new Group II containing claims 10-14. However, these methods (in group I and II) are practiced with materially different starting materials and have materially different process steps. Thus, the restriction between Groups I and II is maintained.

Drawings

3. The drawings are objected to by the draftsperson (see attached PTO 948).

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4a. The term "preferentially" in claim 1 is a relative term which renders the claim indefinite. The term "preferentially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in

the art would not be reasonably apprised of the scope of the invention. Claims 2-5 are rejected insofar as they depend on the above rejected claims.

4b. Claim 6-9 and 13 are rejected as indefinite for reciting "POMC" without explanation. For clarity, an abbreviation should be spelled out in full the first time it appears in the claim.

5.The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5a.Claims 1, 6, 15 and 17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the identification of the compounds that regulate the melanocortin 2-receptor (MC2-R) and melanocortin 5-receptor (MC5-R) activity, does not reasonably provide enablement for identification of compounds that regulate the body weight. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to the invention commensurate in scope with these claims.

The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. See In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404. The factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to: (1) the breadth of the claims; (2) the nature of the invention; (3) the state of the prior art; (4) the level of one of ordinary skill; (5) the level

of predictability in the art; (6) the amount of direction provided by the inventor; (7) the existence of working examples; and (8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Applicants are enabled for methods of screening for compounds useful in the regulation of MC2-R, MC4-R and MC5-R. However, they are not enabled for methods for identifying compounds that regulate body weight. The claims broadly recite the "identification of compounds that regulate body weight." The applicant describes methods which can be used to identify compounds that regulate MC2-R, MC4-R and MC5-R. The disclosure does not teach how the compounds identified can be used to regulate body weight with reasonable expectation that they would have the desired effect. There is no guidance provided in the instant specification as to how one of ordinary skill in the art would correlate the compounds identified that regulate MC2-R and MC5-R with weight regulation. Thus, undue amount of experimentation would be required to use these compounds in weight regulation.

Given the breadth of claims 1, 6, 15 and 17 in light of the unpredictability of the art as determined by the number of working examples, the level of skill of the artisan, and the guidance provided in the instant specification and the prior art of record, it would require undue experimentation for one of ordinary skill in the art to make and use the claimed invention. Claims 2-5,7-9 and 16 are rejected insofar as they depend on the above rejected claims.

5b.Claim 19 is ejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the identification of the compounds that regulate the

melanocortin 2-receptor (MC2-R) and melanocortin 5-receptor (MC5-R) activity, does not reasonably provide enablement for identification of compounds that regulate the peripheral pathways of energy homeostasis. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to the invention commensurate in scope with these claims.

Applicants are enabled for methods of screening for compounds useful in the regulation of MC2-R, MC4-R and MC5-R. However, they are not enabled for methods for identifying compounds that regulate peripheral pathways of energy homeostasis. The claims broadly recite the " regulation of the peripheral pathways of energy homeostasis." The applicant describes methods which can be used to identify compounds that regulate MC2-R and MC5-R. The disclosure does not teach how the compounds can be used to regulate peripheral pathways of energy homeostasis with a reasonable expectation that they would have the desired effect. There is no guidance provided in the instant specification as to how one of ordinary skill in the art would correlate the compounds identified that regulate MC2-R and MC5-R with regulating the peripheral pathways of energy homeostasis. Thus, undue amount of experimentation would be required to use these compounds for regulating the peripheral pathways of energy homeostasis.

Given the breadth of claim 19 in light of the unpredictability of the art as determined by the number of working examples, the level of skill of the artisan, and the guidance provided in the instant specification and the prior art of record, it would require undue experimentation for one of ordinary skill in the art to make and use the claimed

invention. Claims 20 and 21 are rejected insofar as they depend on the above rejected claims.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6a. Claims 1-9 and 15-21 are rejected under 35 U.S.C. 103(a) as being unpatenable over Lee et al. (U.S. Patent No. 5,932,779) in view of Boston et al. (1996).

The instant invention is directed to a method for identifying compounds that regulate body weight by regulating the peripheral pathway of energy homeostasis.

Lee et al. teaches the use of cellular and non-cellular assays to identify compounds that interact with melanocortin 4-receptor (MC4-R) to modulate the activity

(column 7, lines 42-45). In screening for compounds that act as antagonists of MC-4R they have included several pro-opiomelanocortin (POMC) derived peptides like α-MSH and β-MSH, ligands that activate MC-4R to test for inhibition of signal transduction by the test compound as compared to vehicle controls (column 11, lines 12-16).

Lee et al. teach the linking of the regulatory elements of the MC-4R gene to a reporter molecule and using it in appropriate intact cells, cell extracts or lysates to identify compounds that modulate MC-4R gene expression (column 13, lines 11-14). They also teach the evaluation of the melanocortin receptor activity by measuring transcription, translation, phosphorylation, ligand binding activity and G protein activation (column 13, lines 36-63). Although Lee et al. does not teach the measurement of melanocortin receptor translocation within a cell, lipolysis of a cell and fatty acid uptake of the cell, these are art recognized methods to evaluate receptor activity and test compounds that affect lipolysis and/or free fatty acid uptake (specification page: 75, line 6-26). To identify compounds that regulate MC-4R translation, cells or in vitro cell lysates containing MC4-R transcripts are tested for modulation of MC4-R mRNA translation. To assay for inhibitors of MC4-R translation, test compounds are assayed for their ability to modulate the translation of MC4-R mRNA in vitro translation extracts (column 13, lines 24-29). However, Lee et al. does not expressly disclose the identification of compounds that regulate MC2-R and MC5-R in order to regulate the peripheral pathways of energy homeostasis. They also to do not disclose the identification of the compounds using isolated adipocytes.

Boston et al. (1996) discloses the expression of MC2-R and MC5-R receptors in the peripheral tissues such as adipose tissue (see abstract). These receptors are modulated by many melanocortin peptides in adipocytes (page 2043, 1st and 2nd paragraph). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the methods disclosed in Lee et al. to identify compounds that regulate MC2-R and MC5-R receptors described in Boston et al. One of ordinary skill would have been motivated with reasonable expectation of success to modify the methods of Lee et al. because Boston et al. teach that MC2-R and MC5-R receptors expressed in the adipose tissue maybe involved in the regulation of fat storage in the adipose tissue, thus modulating the energy homeostasis by lipolysis (page 2049, 3rd paragraph). In addition, unlike MC4-R receptors which are expressed in the brain, the MC2-R and MC5-R receptors, which are expressed in the adipose tissue, are more easily accessible for energy metabolism regulation. Therefore, the instant invention is *prima facie* obvious over Lee et al. (U.S. Patent No. 5,932,779) in view of Boston et al. (1996).

7. No claims are allowable.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon whose telephone number is 703-305-1112. The examiner can normally be reached on M-F: 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 703-308-4623. The fax phone numbers for

the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and 703-308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

JS
July 2, 2001

JEFFREY STUCKER
PRIMARY EXAMINER

Attachment for PTO-948 (Rev. 03/01, or earlier)
6/18/01

The below text replaces the pre-printed text under the heading, "Information on How to Effect Drawing Changes," on the back of the PTO-948 (Rev. 03/01, or earlier) form.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the Notice of Allowability. Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136(a) or (b) for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit the drawing corrections within the time period set in the attached Office communication. See 37 CFR 1.85(a).

Failure to take corrective action within the set period will result in **ABANDONMENT** of the application.